



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0329]

Center for Devices and Radiological Health: Health of Women Program; Public Workshop;
Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

Summary: The Food and Drug Administration (FDA) is announcing the following public workshop: "The Center for Devices and Radiological Health (CDRH) Health of Women (HoW) Program: Educate, Enable, Enlist and Explore--HoW to Improve the Health of Women." CDRH is developing the HoW Program to explore unique issues in the regulation of medical devices related to the health of women and seeks public input on the priority activities. The CDRH HoW program seeks to bring together industry, clinicians, researchers, academia, government agencies, and patient/advocacy groups in an effort to: (1) Highlight device-specific clinical Study recruitment and retention strategies; (2) improve analysis and communication of sex-specific findings to providers and patients; (3) develop a priority research road map for the HoW device ecosystem. The workshop focus will be device- and disease-specific, patient centered, and action oriented.

Dates and Times: The public workshop will be held on June 24, 2013, from 8 a.m. to 5 p.m. and June 25, 2013, from 8 a.m. to 5 p.m.

Location: The public workshop will be held on FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993.

Contact:

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Registration: Registration is free and available on a first-come, first-served basis.

Persons interested in attending this public workshop must register online by 5 p.m. on June 14, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration will be provided beginning at 7:30 a.m. on the day of the public workshop.

If you need special accommodations due to a disability, please contact Joyce Raines (Joyce.Raines@fda.hhs.gov or 301-796-5709) by 5 p.m. on June 14, 2013.

To register for the public workshop, please visit FDA's Medical Devices News & Events-Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> and select this public workshop from the posted events list. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, telephone number and primary HoW Program area of expertise or interest. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the public workshop: The plenary portions of this workshop will be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. on June 14, 2013. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and connection access information after June 19, 2013. An archived file of the Webcast will be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list).

Workshop format: This workshop will begin with plenary sessions to outline the three primary areas of focus for the CDRH HoW Program. In each area, panels will examine major themes using data-driven case studies with a focus on practical strategies relevant to particular challenges in the medical device arena. Participants will then rotate through breakout sessions, collectively building an action plan for each activity area. The meeting will conclude with

specific commitments by stakeholder groups to partner with CDRH and each other in a collaborative effort to educate, enable, enlist and explore, with a common goal of improving the health of women.

Comments: In order to permit the widest possible opportunity to obtain public information from interested persons on the workshop topics, FDA is opening the docket to gather electronic or written comments on the three areas of focus for the HoW workshop identified in section II. Comments received will be reviewed by FDA as part of this effort. The deadline for submitting comments related to this public workshop topic is July 31, 2013.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics as outlined in section II, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

The mission of the CDRH Health of Women (HoW) Program:

To improve the health of women by:

- Improving the availability, consistency, and communication of sex-specific information for the safe and effective use of medical devices in women;

- addressing identified gaps and unmet needs through targeted resources; and
- fostering the development of innovative strategies, technology, and clinical study paradigms.

A key priority in regulatory science for CDRH is improving the health of special populations and addressing their unique health-related issues.¹ CDRH recognizes women as a special population, and seeks to identify and address differences in the safety, effectiveness, and utilization of medical devices for women. There are unique issues in the regulation of medical devices for use by women, which include:

- Uncertainty about medical device performance in women due to inconsistent data analysis and under-representation of women in clinical trials
- Baseline differences in anatomy, physiology, risk factors, disease signs/symptoms, and comorbidities that may be associated with different outcomes of device use
- Potential differences in health communication/health seeking behavior that may impact FDA communication of medical device benefit-risk information to this population
- Different considerations regarding effects of hormones through life stages (first menstrual period (menarche) to menopause; hormone replacement therapy)
- Unique risks and needs related to medical device research involving women of childbearing potential
- Unique risks and needs for pregnant females associated with the use of medical devices, including risk of birth defects (teratogenicity) or complications of pregnancy arising from medical device components such as drugs, chemicals, and certain biomaterials

II. Topics for Discussion in the Docket and at the Public Workshop

¹ Food and Drug Administration, “Regulatory Science in FDA’s Center for Devices and Radiological Health: A Vital Framework for Protecting and Promoting Public Health,”
<http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm274162.pdf>.

Topics for discussion include:

1. Device-specific clinical study recruitment and retention strategies;
2. Analysis and communication of sex-specific findings to providers and patients; and
3. Priority research road map for the HoW device ecosystem.

Dated: April 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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